



## ZIKA VIRUS

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### 1) COMMERCIAL FAQS RELATED TO ZIKA VIRUS

#### 1. How are health and sanitary related products regulated and approved in Brazil?

The Brazilian Ministry of Health regulates all products that affect the human body, including pharmaceuticals, vitamins, cosmetics, repellants and medical diagnostic equipment and devices through the National Agency for Sanitary Surveillance (ANVISA), FDA's counterpart. Such products can only be imported and sold in Brazil if the foreign company appoints a Brazilian distributor who is authorized by the ANVISA to import and distribute medical products, or the foreign company establishes a local Brazilian manufacturing unit or local office. In addition, these products must first be registered with ANVISA via one of the aforementioned ANVISA approved entities. Due to extensive, complex and frequent changes in regulations, U.S. companies may also consider working with companies specialized in the ANVISA product registration process [see some offices specialized in registration of products](#).

#### 2. Does ANVISA (FDA counterpart) have a streamlined process to review and approve products for commercial sale into Brazil?

The ANVISA registration and market approval process can take anywhere from 45 to days to 24 months depending on the type of product. However, ANVISA recently announced that it would prioritize the technical analysis of product registration requests for products, which have applications for preventing, treating and combatting the Zika virus, e.g., repellents, diagnostics and vaccines. U.S. exporters will need to work with a legally established Brazilian entity and should indicate that the product has an application for the Zika virus. U.S. companies may also consider working with companies specialized in the ANVISA product registration process.

#### 3. How long does it take to clear equipment at customs?

The Brazilian customs clearing process depends on several factors but varies from five to twenty days. Some key factors that affect the clearance process are the type of product, the required import licenses and the location of importation (port, airport).

#### **4. Can the U.S. Government assist with clearing customs?**

The Brazilian government has established by law the customs clearing process, which is managed by Brazilian Customs, a government entity that is part of the Brazilian Internal Revenue Service (Receita Federal). Therefore, the U.S. Government does not get involved in the customs clearing process (USG may request that the GOB assist in clearing customs of products from the U.S. under very extenuating circumstances). There are many accredited customs brokers and agents that can assist U.S. companies with the customs clearance process in Brazil. Please see list [below](#).

#### **5. Is there an expedited process to clear customs?**

It is possible that specific products under unique circumstances may be given a priority review for customs clearance. In some cases, ANVISA and the Brazilian Internal Revenue Service may prioritize custom clearance through a petition from the Brazilian representative of the imported product to ANVISA and the Internal Revenue Service.

#### **6. How can I sell my product to the Brazilian Government?**

The law 8.666/93 established a regulatory framework for the Brazilian Government procurement process. The standard model used for international biddings is a competitive bidding process ("concorrência"), in which the lowest bid is given preference over all other suppliers' bids. All documents must be authenticated by the Brazilian Consulate and translated by a Brazilian accredited translator. Foreign companies must have a Brazilian legal representative that has power of attorney and is legally liable and responsible for the company. For more details on the federal procurement law, please see [http://www.planalto.gov.br/ccivil\\_03/leis/L8666cons.htm](http://www.planalto.gov.br/ccivil_03/leis/L8666cons.htm)

#### **7. Can the U.S. Government assist in bringing specific products to the attention of Brazilian government officials?**

The U.S. Commercial Service at the U.S. Embassy in Brazil has a number of services that U.S. companies can use to promote their products and services to the Brazilian Government. The following are just a few examples of services offered to U.S. companies: Commercial Advocacy, identification and qualification of key decision makers and scheduling of appointments with government officials. For full details on U.S. Commercial Service offerings in Brazil please visit <http://export.gov/brazil/ourservices/index.asp>

#### **8. How can I sell my products to the Rio Olympic Committee?**

To participate in the Olympic Organizing Committee tenders for the Rio Olympics U.S companies must do the following:

1) Pre-register at the Rio 2016™ procurement link:  
<http://portaldesuprimentos.rio2016.com/en/registration/>

2) Register at website: <http://portaldesuprimentos.rio2016.com/en/>  
Current tenders are located on the procurement page, under the title “Suppliers Portal Status of the Bids”, at: <http://portaldesuprimentos.rio2016.com/en/status-of-the-bids/>.

For further information, please contact:

Patrick Levy, Business Development Specialist  
U.S. Consulate General, Rio de Janeiro  
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[patrick.levy@trade.gov](mailto:patrick.levy@trade.gov)

## **9. What has Brazil done to date to address the outbreak?**

The Brazilian Government (GOB) has allocated 12 billion Brazilian Reais (US\$ 3.15 billion) to combat the Zika virus outbreak and has developed the National Plan in the Fight against *Aedes aegypti* and Microcephaly. The Plan includes the following objectives:

- Coordinate efforts among several Federal Ministries in partnership with state and municipal governments.
- Inform citizen through communication blitz: December 2015 to June 2016.
- Inspect all households and public and private urban facilities by February 2016.
- Intensify mosquito control visits through bi-monthly home inspections.
- Mobilize for the combat against the *Aedes aegypti* mosquito.
- Provide medical care for citizens infected with the virus and treatment for microcephaly.
- Conduct research, technology development and education.

To date, the GOB has sent trained teams out to the affected regions to assist in the fight against the outbreak, formed working groups to study Microcephaly cases and engaged in information exchanges with the WHO and the PAHO. The GOB has also deployed 220,000 military troops in the combat against the *Aedes aegypti* mosquito.

The U.S. Government is committed to working with the Government of Brazil to engage in close scientific and public health collaborations to better understand Zika and to expedite the research and development of diagnostics, vaccines, treatments, and vector control techniques. As part of this effort, a delegation of six senior health officials from the U.S. Department of Health and Human Services (HHS) met with their Brazilian counterparts to discuss potential collaboration on epidemiology, surveillance, clinical assessment, maternal health and child development, vector control aspects of Zika, and studies of possible links between Zika and microcephaly and Zika and Guillain-Barre Syndrome. The delegation

was led by HHS Assistant Secretary for Global Affairs Ambassador Jimmy Kolker and included senior officials from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Biomedical Advanced Research and Development Authority (BARDA).

You can access the National Plan against the Zika Virus here: <http://combateaedes.saude.gov.br/plano-nacional>

#### **10. Where can I find more information?**

Please see below for additional resources and information.

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### **2) RESOURCES AND INFORMATION ON THE ANVISA REGISTRATION PROCESS AND REGULATIONS**

ANVISA Website Information

#### **a. Medication**

[FAQs about registration of medications](#)

[Registration of medications](#)

[Medication registration related documents required](#)

#### **b. Vaccines / Biological Products**

[Medication/Biological Products \(Vaccines\)](#)

[FAQs for Biological Products Registration](#)

#### **c. Insecticides**

[Information on Toxicology \(Encompass Insecticides\)](#)

[Required information for registration of insecticide](#)

[FAQs on the use of insecticide](#)

#### **d. In Vitro Diagnostics**

[In Vitro Diagnostics Products \(Diagnoses from Human Samples Products\)](#)

[In Vitro Diagnostics Products Importer and Manufacturer Orientation](#)

[In Vitro Diagnostics Products Regularization Guide](#)

**e. Repellants**

[Grade 2 Cosmetic List \(repellants are #51\)](#)

[Cosmetic Safety Resource Guide](#)

[RESOLUTION - RDC Nº 4, January 30, 2014: Technical Requirements Resolution for Cosmetics](#)

**f. Active Pharmaceutical Ingredients**

[Active Pharmaceutical Ingredients Registration information](#)

[Registration procedures for Active Pharmaceutical Ingredients](#)

**g. ANVISA Import Information**

[ANVISA - Imports of products subject to sanitary control](#)

Resolution RDC nº 81, November 5, 2008: [This document provides information on Brazilian health surveillance technical regulations for imported products](#)

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**Private Sector Website Resources**

Detailed information on regulations and registration process:

<http://www.emergogroup.com/resources/regulations-brazil>

<http://www.emergogroup.com/search/gss/anvisa>

Brazilian Chamber for In Vitro Diagnostics Products - CBDL:

<http://www.cbdl.com.br/>

Brazilian Association for cleaning products - ABIPLA

<http://www.abipla.org.br/novo>

Brazilian Association for Cosmetics and Personal Hygiene Products - ABIHPEC

<https://www.abihpec.org.br/>

Brazilian Association for Medical, Dental and Laboratorial Equipment ABIMO:

<http://abimo.org.br/>

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### **3) COMPANIES SPECIALIZED IN ANVISA PRODUCT REGISTRATION**

(Disclaimer: this list is not an endorsement or recommendation but rather a non-exhaustive list of companies specialized in these activities that the U.S. Commercial Service is aware of.)

Bastos Tigre Associados (Sao Paulo)  
Luciano Campeão, Associated Lawyer.  
[luciano@bastostigre.adv.br](mailto:luciano@bastostigre.adv.br)  
+55 11 3067 3414

Emergo Group (Sao Paulo/Brasília)  
Marcelo Brisolla, Managing Director Brazil.  
[mb@emergogroup.com](mailto:mb@emergogroup.com)  
Office +55 61 3386-3166

Latini & Associados (Sao Paulo)  
Roberto C. Latini, Director  
+55 11 5090-5080  
[rlatini@latini.com.br](mailto:rlatini@latini.com.br)  
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Vera Rosas (Sao Paulo)  
+55 11 3280-9397  
[comercial@verarosas.com.br](mailto:comercial@verarosas.com.br)  
[www.verarosasregistro.com.br](http://www.verarosasregistro.com.br)

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### **4) COMPANIES AND AGENCIES SPECIALIZED IN CUSTOMS BROKERS** (Disclaimer: this list is not an endorsement or recommendation but rather a non-exhaustive list of companies specialized in these activities that the U.S. Commercial Service is aware of.)

TECIMPORTS  
Alexandre de Souza Rego, Foreign Trade Department  
+ 55 11 3809-6870  
[alexandre@tecimports.com](mailto:alexandre@tecimports.com)  
[www.tecimports.com](http://www.tecimports.com)

Thomaz Comissaria  
Walter Thomaz  
+ 55 11 3331-2144

walterjr@thomazcomissaria.com.br  
www.thomazcomissaria.com.br

Deicmar – Serviços Logísticos  
Paulo Games, Integrated Logistics  
+ 55 13 3131-1068  
paulo.games@deicmar.com  
www.deicmar.com

XPO Group  
+55 11 2359-2318  
www.xpolog.com.br

Logger Cargo  
+ 55-11-2506-4180  
www.logercargo.com.br

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#### **5) 3<sup>RD</sup> U.S. HEALTH IT TRADE MISSION TO BRAZIL INFORMATION**

The U.S. Commercial Service is organizing the **3<sup>rd</sup> U.S. Health IT Trade Mission to Brazil**, on September 26 to 30, 2016. This event will be held in São Paulo and Recife, to discuss the transformation of the healthcare environment in Brazil. Seminars, roundtables, networking receptions, tours to largest hospitals and the opportunity to meet thought leaders, CIOs, representatives of the public and private entities. For further information, please visit the website:

<http://export.gov/brazil/industryhighlights/healthit/index.asp>

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#### **6) CONTACTS AT THE U.S. COMMERCIAL SERVICE**

**For further information, please contact the U.S. Commercial Service in Brazil:**

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+ 55 11 3250-5402 / [everett.wakai@trade.gov](mailto:everett.wakai@trade.gov)

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